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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/597,513	06/20/2000	Alan Collmer	19603/3306 (CRF D-2136B)	5828

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EXAMINER

KUBELIK, ANNE R

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 06/17/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/597,513

Applicant(s)

COLLMER ET AL.

Examiner

Anne Kubelik

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. The amendments to the specification, the cancellation of claims 11-16 and 29-37, and the amendment of claims 1-7 and 9-10 requested in paper No. 11, filed 1 April, 2002, have been entered. Claims 1-10 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

Applicant's arguments filed 28 March, 2002, have been fully considered but they are not persuasive. Applicant urges that the corrections made by Amy Charkowski were made at the time she signed, and that the declaration was accepted in the parent application.

This is not found persuasive because these alterations were not made to all signed copies of the declaration and the date was not included with the initials.

4. The draftsman has approved the drawings as submitted.
5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

The figure legend of Figure 2C must contain the sequence identifiers for all the sequences listed in the figure.

Full compliance with the sequence rules is required in response to this Office action. A complete response to this Office action must include both compliance with the sequence rules

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and a response to the issues set forth below. Failure to fully comply with both of these requirements in the time period set for in this Office action will be held to be non-responsive.

***Response to Amendment***

6. The rejections of claims 1-10 under 35 U.S.C. 102(b) as being anticipated by Lorang et al and claims 1-16 and 29-31 under 35 U.S.C. 103(a) as being unpatentable over Bauer et al in view of Lorang et al are WITHDRAWN in light of amendments to claim 1 to indicate that the DNA molecule is from a source other than *Pseudomonas syringae* pv *tomato*.

***Claim Rejections - 35 USC § 112***

7. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Neither the instant specification nor the originally filed claims appear to provide support for the phrase “a DNA molecule from a source other than *Pseudomonas syringae* pv *tomato*”. Thus, such phrase constitutes NEW MATTER. In response to this rejection, Applicant is required to point to support for the phrase or to cancel the new matter.

8. Claims 1 and 4-10 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids of SEQ ID NO:1 or encoding SEQ ID NO:2, does not reasonably provide enablement for nucleic acids that hybridize under conditions of unspecified stringency to SEQ ID NO:1 or for expression of nucleic acids that encode SEQ ID

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NO:2 or hybridize to SEQ ID NO:1 in plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the last Office action mailed 17 December, 2001, as applied to claims 1-16 and 29-31.

Applicant's arguments filed 28 March, 2002, have been fully considered but they are not persuasive. Applicant urges that the claims have been amended to recite specific hybridization conditions. Applicant argues that HR can be tested by applying protein the plant leaves, as described in Gopalan et al, included by Applicant. Applicant argues that HR elicitors share the characteristics of being glycine rich, heat stable, hydrophilic, a lacking cysteine, as cited in each of Bonas (1994-I), Bonas (1994-II), and Preston et al, included by Applicant. Applicant also states that SEQ ID NO:1 hybridized to many strains and species of *Pseudomonas*, as described in Example 10 (response pg 7-8).

This is not found persuasive because hybridization time and wash conditions are not recited in the claims. Additionally, the references included in the response were not cited in the specification.

As stated in the prior Office action, expression of *hrp* genes in plants is unpredictable. As constitutive elicitor production can be lethal to a plant, producing disease resistance via transformation with a gene encoding an elicitor protein also requires a pathogen-induced promoter (Keller et al, 1999, Plant Cell 11:223-235, see pg 224, left column paragraph 1). This is illustrated by Bauer et al (1999, Acta Hort. 489:301-304), who showed that while *Arabidopsis* plants transformed with the *hrpN* gene expressed behind a pathogen-inducible promoter were

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resistant to downy mildew, those transformed with the *hrpN* gene expressed behind a constitutive promoter were not (pg 302, paragraphs 5-6). In fact, constitutive expression of *hrpN* in these latter plants resulted in physical damage to the plants (pg 302, paragraph 6). Bauer et al also showed that the *hrpN* construct must be expressed with a signal sequence for export of the protein from the plants cells for production of resistant plants to be successful (pg 302, paragraph 5). The instant specification fails to teach the necessity for inducible promoters or how lethality or plant damage can be prevented without them, and it fails to teach the need for signal sequences for protein export.

9. Claims 1 and 4-10 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the last Office action mailed 17 December, 2001, as applied to claims 1-16 and 29-31.

Applicant's arguments filed 28 March, 2002, have been fully considered but they are not persuasive. SEQ ID NO:1 has been characterized as has the protein it encodes, and this protein shares the characteristics of other hypersensitive response elicitors. Applicant also argues that the nucleic acid of SEQ ID NO:1 hybridizes to nucleic acids in other *Pseudomonas* species and that a single species is representative of the claimed genus (response pg 8-9).

This is not found persuasive because hybridization times and wash conditions are not cited in the claims. Additionally, the function of the encoded protein, *i.e.*, the activity of the enzyme, is not recited.

See *In re Shokal*, 113 USPQ 283, (CCPA 1957) at pg 285

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It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. In re Soll, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; In re Wahlforss et al., 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary. ...

We are of the opinion that a genus containing such a large number of species cannot properly be identified by the mere recitation or reduction to practice of four or five of them. As was pointed out by the examiner, four species might be held to support a genus, if such genus is disclosed in clear language; but where those species must be relied on not only to illustrate the genus but to define what it is, the situation is otherwise.

10. Claims 1-10 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is repeated for the reasons of record as set forth in the last Office action mailed 17 December, 2001, as applied to claims 1-16 and 29-31.

Applicant's arguments filed 28 March, 2002, have been fully considered but they are not persuasive. Applicant urges that the rejections are traversed (response pg 10).

This is not found persuasive. Claims 1 and 4 are indefinite for their recitation of "a DNA molecule from a source other than *Pseudomonas syringae* pv *tomato* which hybridizes to a DNA molecule comprising the complement of SEQ ID No. 1 under conditions" in part (c). It is not clear if "under conditions" is intended to modify "SEQ ID No:1", "complement", "sequence" or "hybridizes". The hybridization conditions are indefinite because hybridization time and wash conditions are not recited.

### ***Claim Rejections - 35 USC § 102***

11. Claims 1 and 4-10 remain rejected under 35 U.S.C. 102(a) as being anticipated by Tabakaki et al (1997, Devel. Plant Biol. 9:392-396). The rejection is repeated for the reasons of

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record as set forth in the last Office action mailed 17 December, 2001, as applied to claims 1-12 and 14-15.

Applicant's arguments filed 28 March, 2002, have been fully considered but they are not persuasive. Applicant urges that Tabakaki et al does not describe a nucleic acid as recited in claim 1. This is not found persuasive because hybridization times and wash conditions are not recited in the claims.

12. Claims 1 and 4-10 remain rejected under 35 U.S.C. 102(e) as being anticipated by Bauer et al (US Patent 5,850,015, filed June, 1995). The rejection is repeated for the reasons of record as set forth in the last Office action mailed 17 December, 2001, as applied to claims 1-16 and 29-31.

Applicant's arguments filed 28 March, 2002, have been fully considered but they are not persuasive. Applicant urges that Bauer et al does not describe a nucleic acid as recited in claim 1. This is not found persuasive because hybridization times and wash conditions are not recited in the claims.

### *Claim Objections*

13. Claims 2-3 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form.

### *Conclusion*

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Kimberly Davis, at (703) 305-3015.

Anne R. Kubelik, Ph.D.

June 12, 2002

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180-1638

